REMARKS

Reconsideration of the instant application is respectfully requested in view of the foregoing amendments. Claims 1 to 6 have been canceled, without prejudice, and claims 7 to 14 have been amended. No newly added claims are presented.

The specification has been amended to properly identify the registered trademarks PROVIGIL®, MODIADAL® and VIGIL®, as the Examiner requested.

In the Office Action dated May 17, 2006, previously pending claims 7 to 14 were rejected. To the extent that the Examiner would apply the cited references to the claims as presently amended, Applicants respectfully traverse.

Independent claim 7, as amended herein, is directed to an oral pharmaceutical composition comprising modafinil particles, colloidal silicon dioxide, crospovidone and povidone, said composition having a dissolution rate in 0.1N HCl at 37°C of more than 80% in 30 minutes. Claim 7 further recites that at least about 5% of the cumulative total of said modafinil particles have a diameter of more than about 250μ.

Several of the previously pending claims were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to specify the solvent and temperature used to define dissolution rates. Amended claim 7 defines these variables (0.1N HCl and 37°C, respectively). Support for these recitations may be found, for example, at page 8, Example 4. Other claims were rejected as indefinite based on the use of trademarks in the claims. Applicants have deleted all reference to trademarks in the claims. In particular, claim 14 now specifies that the composition is bioequivalent to the modafinil drug identified by the Food and Drug Administration as the reference listed modafinil drug. The Food and Drug Administration identifies PROVIGIL® 200 mg tablets as the reference listed modafinil drug, as shown in the attached page from the FDA Orange Book website (*see*, http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=020717&TABLE1=OB_Rx). Applicants respectfully submit that these amendments render the rejections under Section 112, second paragraph moot.

The Office Action also asserted that the previous claims were anticipated or obvious over Grebow et al., U.S. Patent No. 5,618,845 ("Grebow") or Heacock et al., U.S. 2004/0048931 ("Heacock"). As correctly noted in the Office Action, Grebow does not

describe compositions wherein at least about 5% of the cumulative total of said modafinil particles have a diameter of more than about 250μ. Moreover, Grebow does not teach the use of dissolution modifiers to control the rate at which the product dissolves. Rather, Grebow teaches that dissolution rate is to be controlled by the use of particles having a particular size distribution, which is outside the size distribution recited in the amended claims. Accordingly, it is respectfully submitted that the amended claims are neither anticipated nor rendered obvious by Grebow.

Applicants' amended claims also define over Heacock. Like Grebow, Heacock focuses primarily on the use of particle size modification to control dissolution, and hence bioavailability. In particular, Heacock does not describe any compositions that contain colloidal silicon dioxide, crospovidone or povidone (much less all three), as recited in the amended claims. Since Heacock fails to describe all of the elements of Applicants claims, it is respectfully submitted that the claims are patentable over Heacock.

Accordingly, Applicants respectfully request that the rejections over Grebow and Heacock be withdrawn. There being no further issues remaining, a Notice of Allowance for all of pending claims 7 to 14 is respectfully solicited.

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